

Remarks:

This amendment is submitted in an earnest effort to advance this case to issue without delay.

The rejection of claim 39-41 under §112 has been avoided by elimination of the references to "modes" as well as a "narrow" and "broad" range. In particular the "broad" range is now defined as being between 1 Hz and 100 Hz and the "narrow" range is that band within that range that resonates with and excites brain activity of the patient.

Claim 1 has been amended by insertion into it of the word "single" to clarify that a single reset pulse is originally used.

Method claims 42-45 have been added to the case. Claims 43-45 are identical in scope to apparatus claims 39-41 and claim 42 is identical in scope to claim 1. The unity-of-invention rule (37 CFR 1.475) applicable to PCT cases clearly allows method and apparatus claims in the same application.

In general the new rejection shows that little weight has been given to the various technical features specified in claims 1 and 42. For instance ¶5 of the Office Action, which was straight out of the previous action as shown by the incorrect numbering,

completely ignores that the function of the periodic succession of pulses is to control the phase dynamic of the neuronal rhythmic activity and the function of the pulse following the periodic succession of pulses is to desynchronize the neuronal rhythmic activity. These features are essential features of the invention, in particular because none of the cited prior art documents teach a periodic succession of pulses that controls the phase dynamic of the neuronal rhythmic activity and a pulse that desynchronizes the neuronal rhythmic activity. Moreover, the prior art documents even do not suggest that visual, acoustic or tactile pulses can be used to treat or even desynchronize neuronal rhythmic activity.

Since the functions defined in the "means for" parts of the claims seem to be being ignored, the new method claims, where ignoring them is harder, have been proposed.

With respect to amended claims 39-41, in patients with neurological or psychiatric disorders, such as Morbus Parkinson, essential tremor, dystonia or compulsion disorders, certain neuron populations in the brain become pathologically active, for example, excessively synchronous in their activity. In this case a large number of neurons generate action potentials synchronously and fire predominantly synchronously. In addition, the neurons of the affected population have an oscillatory activity, that is they fire in a rhythmic manner. With healthy individuals, by contrast, the

neurons fire qualitatively differently, for example in an uncontrolled, non-synchronous manner.

The invention is based on the discovery that suitable visual, acoustic or tactile stimulation may lead to desynchronizing the affected neuron population. In order to be effective, the visual, acoustic or tactile stimulus that causes the desynchronization needs to be applied at a critical phase of the collective oscillation of the neuron population. This critical phase is also called the vulnerable phase.

In order to be able to hit the neuron population at the vulnerable phase, complex stimuli are used that are composed of two qualitatively different stimuli. These stimuli are shown by way of example in FIG. 2 of the application. The first stimulus is a so-called entraining periodic pulse sequence that controls the dynamics of the neuron population. This means that after the application of the entraining pulse sequence the neurons still have a synchronous and rhythmic activity, but the dynamics of the neuron population is now in step with the entraining periodic pulse sequence. Since the phase of the activity of the neuron population is now known, the second stimulus can be applied such that it hits the neuron population at the vulnerable phase and thus desynchronizes the neuron population.

In order to generate this complex stimulus, the frequency of the entraining periodic pulse sequence as well as the vulnerable phase need to be determined. The frequency of the entraining

periodic pulse sequence is determined by using a frequency scan as is shown in FIG. 4 of the application. To this end, a pulse sequence is applied whose frequency is varied (cf. FIG. 4a), and at the same time the brain activity is measured to determine a frequency range that resonates with and excites neuronal activity of the patient (cf. FIG. 4b). The determined resonance frequency, which is a frequency of the pulse sequence that causes the greatest excitation of the neuronal activity, is selected as the frequency of the entraining periodic pulse sequence.

The vulnerable phase at which the desynchronizing second stimulus is applied, corresponds to the time delay between the last pulse of the entraining periodic pulse sequence and the desynchronizing second stimulus. Furthermore, in order to be effective, the second stimulus needs to have a certain intensity. The optimal value of the interval between the entraining pulse sequence and the second stimulus as well as the optimal value of the intensity of the second stimulus is determined by varying these two parameters while applying several entraining pulse sequences together with a successive desynchronizing pulse.

Getting back to new claims 39 to 41, the first "means" is the "means for carrying out a frequency scan" mentioned in paragraph [0050] of the published application and the second means is the "means for determining the vulnerable phase" mentioned in paragraph [0082]. According to paragraph [0052] ("This frequency

scan can be carried out by the control 4...) and paragraph [0083] ("The variation of the time spacing and the intensity is carried out preferably by the control unit 4.") the first and second means are part of the control unit.

Paragraph [0047] discloses that the first means applies the pulses with the stimulator to the patient with a pulse frequency varying between 1 and 100 Hz. While varying the pulse frequency the sensor means monitors brain activity to determine in which frequency range the brain activity develops an excitation.

The frequency range determined by the first means is the frequency range of the entraining (first) stimulus. Paragraph [0083] says that the second means generates with the stimulator a series of pulses within the determined frequency range (i.e. the entraining stimulus) followed after an interval by a single pulse and varies the length of the interval while monitoring with the sensor means brain activity of the patient to determine an interval at which the strongest desynchronization of pathologically rhythmic brain waves of the patient is effected. The determined interval corresponds to the vulnerable phase.

Claim 40 specifies that the second means also varies an intensity of the single pulses in order to determine an intensity at which the strongest desynchronization of pathologically rhythmic brain waves is effected. This feature is also disclosed in paragraph [0083].

In claim 41 the application of the complex stimulus including all previously determined parameters is claimed, i.e. the determined frequency range, the determined intensity and the determined interval. The features of claim 41 are disclosed in paragraphs [0065] and [0066].

Claim 39 is rejected on US 3,780,724 of John, expect for the stimulation of a series of pulses within a narrow frequency determined to provide the greatest brain excitation. The feature acknowledged to be missing from John by the Examiner is a part of the function of the second means specified in claim 39.

It is true that the cited feature is not disclosed by John. In contrast to the Examiner, however, John does not disclose the first means specified in claim 39 either. The first means of claim 39 has not been included in the claims previously in the case, so it repetition of this same rejection with respect to the new claims is in error. The feature which comes closest to the first means is the frequency scan specified in original claim 7. The Examiner states that John discloses a frequency scan in column 4, lines 15-20 (cf. point 7 of the Office Action).

The prior art document by John concerns the testing of neuronal responses to visual, acoustic, or tactile stimuli. The electrical responses of the brain to these stimuli are detected by electrodes attached to the head of the patient and amplified by an EEG. In the test described in the text passage cited in the

rejection a stimulus group is repeatedly presented to the patient and at the same time the evoked response is monitored to determine when it is greater than a predetermined test standard. As soon as the predetermined test standard is reached, the test computer will send out its result to a recorder and the remaining sweeps may be omitted (cf. column 4, lines 26-34).

John, however, does not disclose varying the pulse frequency, in particular between 1 and 100 Hz, and determining in which frequency range the brain activity develops an excitation.

Furthermore, John does not teach using the frequency range determined by the first means for generating a series of synchronizing pulses that resonate with brain activity. John does also not teach that the series of pulses is followed after an interval by a single pulse and the length of the interval is varied to determine an interval at which the strongest desynchronization of pathologically rhythmic brain waves of the patient is effected.

The rejection argues that the function of the second means is simply the finding the most effective stimulation of the patient and is commonly performed in various medical procedures. Even if it may be a standard procedure to vary the length of an interval to find the most effective interval, it is not obvious to a person skilled in the art to first find the most effective pulse frequency range and then to use this pulse frequency range for finding the most effective length of an interval between a series

of pulses and a single pulse, wherein the series of pulses have a frequency within the determined frequency range.

Thus the claims in the case are clearly allowable over the cited art. Notice to that effect is earnestly solicited.

If only minor problems that could be corrected by means of a telephone conference stand in the way of allowance of this case, the examiner is invited to call the undersigned to make the necessary corrections.

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